DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
M3415n

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

January 5, 2000

WARNING LETTER
CHI-6-00

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Edward M. Beranek, President
Vitrophage, Inc.
8643 W. Ogden Ave #1-B
Lyons, IL 60534

Dear Mr. Beranek:

During an inspection of your establishment located in Lyons, IL, from November 16 to November 22, 1999, our investigator, Tamara Brey, determined that your establishment manufactures intraocular fluid. Intraocular fluid is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish a complete quality policy and ensure that existing quality procedures are understood, implemented, and maintained.
2. Failure to conduct periodic quality audits to ensure the quality system is in compliance with the establish quality system requirements and to determine its effectiveness.
3. Failure to establish procedures for the following Design Control activities: Design Input, Design Output, Design Review, Design Verification, Design Validation, Design Transfer, and Design Changes.
4. Failure to maintain a current and accurate Device Master Record (DMR). For example, the DMR did not contain the name and address of the supplier for the chemical grade raw material, perfluoroperhydrophenanthrene.
5. Failure to establish procedures to control document changes. Failure to document the approval of procedures. For example, the following documents lacked an approval signature of an individual responsible for approving the document:

- Acceptance and Release of Finished Vitreon
- Complaint Handling
- Quality Assurance Program

6. Failure to conduct periodic audits of suppliers as specified in the Quality Assurance Program.

7. Failure to establish an agreement between the firm and contract manufacturers, sterilizer, and packer of Vitreon®, to notify the firm of changes in the product or manufacturing specifications.

8. Failure to establish procedures for implementing corrective and preventive actions.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA Form 483 issued at the conclusion of the inspection, may be symptomatic of serious underlying problems in your establishment's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

We acknowledge that your firm responded by letter, dated November 29, 1999, to our investigator's FDA-483. We do not consider your firm's response adequate because it did not provide evidence of corrective actions (e.g. draft procedures) and it lacked an estimated completion date for each corrective action that was in process.

We request that you take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Michael Lang, Compliance Officer.

Sincerely,

\s\
Raymond V. Mlecko
District Director